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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/982,474 | 10/17/2001 | Wilhelmus Theodorus Antonius Maria De Laat | 246152012710 | 8056 |

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| EXAMINER |
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WINSTON, RANDALL O

| ART UNIT | PAPER NUMBER |
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1651

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DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|--------------------------------------|---------------------------------------|
| Application No. 09/982,474 | Applicant(s) De Laat et al. |
| Examiner Randall Winston | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8, 15, 16, 19, 20, 36, and 37 is/are pending in the application.

is/are withdrawn from consideration.

4a) Of the above, claim(s) _____ is/are allowed.

5) Claim(s) _____ is/are rejected.

6) Claim(s) 1-8, 15, 16, 19, 20, 36, and 37 is/are objected to.

7) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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DETAILED ACTION

Response to Amendment

The preliminary amendment filed on October 17, 2001 has been entered.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 15-16, 19-20, and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term “chemically defined medium.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning of “chemically defined medium.” There is no definition of “chemically defined medium” in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention because “chemically defined medium” can be interpreted various ways.

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All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 15-16, 19-20 and 36 are rejected under 35 U.S.C. 102 (b) as being anticipated

by Hogye et al. (Derwent 1987-357537).

Applicant claims a process for the production of Beta-Lactam (e.g., penicillin V and/or adipoyl-7-ADCA), comprising the steps of fermenting a microbial strain (e.g., *Penicillium chrysogenum*) that produces a Beta-Lactam in a fermentation medium which is a chemically defined medium consisting of chemically defined constituents (e.g., constituents comprise a carbon source and/or nitrogen source), and recovering the Beta-Lactam.

Hogye et al. anticipate the claimed invention because Hogye et al. teach a process for the production of penicillin V and its recovery comprising of the steps of fermenting *Penicillium chrysogenum* that produces penicillin V in a fermentation medium consisting of chemically defined constituents of a nitrogen source such as ammonium sulphate and an ammonium

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hydroxide and the removal of the fermentation liquor to recover the penicillin V (see, e.g. abstract). Therefore, Hogye et al. anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 15-16, 19-20, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogye et al. (Derwent 1987-357537) in view of Bovenberg et al. (US 5731165).

The primary reference is relied upon for the reasons discussed above. Hogye does not teach a process for the production of adipoyl-7-ADCA comprising of the same steps as described above for the production of penicillin V.

Bovenberg et al. beneficially teach a process for the production of adipoyl-7-ADCA comprising the steps of fermenting *Pencillium chrysogenum* that produces adipoyl-7-ADCA in a fermentation medium consisting of chemically defined constituents of a carbon source such as glucose (see, e.g., example 1).

One of ordinary skill in the art would have been motivated to modify Hogye et al.'s process to include Bovenberg et al.'s process for the beneficial purpose of producing the claimed invention's process of the production of penicillin V and/or adipoyl-7-ADCA because both

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processes utilize the same steps to produce different Beta-Lactams. Differences in conventional result-effective conditions (e.g., amounts and ratios of each active ingredient, fed-batch fermentation and production on a large industrial scale) does not support the patentability of claimed subject matter, unless there is clear and sufficient evidence indicating such working condition(s) is/are critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (see, e.g. MPEP 2144.05). Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

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CHRISTOPHER R. TATE
PRIMARY EXAMINER